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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,558	01/25/2005	Tokuhiro Chano	3190-070	2830

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KILYK & BOWERSOX, P.L.L.C.
400 HOLIDAY COURT
SUITE 102
WARRENTON, VA 20186

EXAMINER	
REDDIG, PETER J	
ART UNIT	PAPER NUMBER
1642	
MAIL DATE	DELIVERY MODE
11/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,558	CHANO ET AL.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5, 8-16,and 18-26* is/are pending in the application.

4a) Of the above claim(s) *1-3, 11-16,and 18-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,5 and 8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed July 25, 2008 in response to the Office Action of April 28, 2008 is acknowledged and has been entered. Claims 4, 9 and 10 have been amended. Claims 4, 5, and 8-10 are currently being examined.

2. The Declaration under 37 CFR 1.132 filed July 25, 2008 is sufficient to overcome the rejection of claims, 4, 5 and 8-10 based upon as being anticipated by Chano et al. (Oncogene, February 14, 2002, 21:1295-1298, IDS) under 35 U.S.C. 102(a).

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 5 remains rejected under 35 U.S.C. 102(b) as being anticipated by Nagase et al. (DNA Research, 1996, 3:321-329) as evidenced by Nomura et al. (DNA Research, 1994: 1: 27-35), essentially for the reasons forth in the Office Action of April 28, 2008, section, 8, pages 7-9.

Examiner argued:

Nagase et al. teach the cloning of the cDNA KIAA0203, which 99.3% identical to SEQ ID NO: 3 and codes for a protein identical to RB1CC1, see Table 1 of Nagase et al. and Appendix 1. Nagase et al. used the methods Nomura et al. for cloning the cDNA, see Materials and Methods and reference 1 of Nagase et al. Nomura et al. teach that cDNA were cloned and placed into the pBluescript SK+ cDNA vector and used to make cDNA libraries that were grown in colonies of cells, see p. 28, 1st col., of Nomura et al.

Chano et al. teach that RB1CC1 can induce the expression of the RB1 gene, see Abstract, Fig. 2 and Fig.4.

Although the reference does not specifically state that KIAA0203 codes for a protein or polypeptide which is present in nucleus of human or animal cell and which has a transcription factor function and /or a function that can induce expression of retinoblastoma gene (RB1 gene) or a gene product thereof, given the teaching of Chano et al. The claimed product appears to be

the same as the prior art product, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA).

Applicants argue that Nagase et al. does not describe a sequence identical to SEQ ID NO: 3. Further, as acknowledged by the Examiner, the reference does not describe a protein or polypeptide which is present in the nucleus of a human or animal cell, or which has a transcription factor function and/or a function that can induce expression of retinoblastoma gene (RB I gene). The Examiner suggests that the teachings of Chano et al. overcome the deficiencies of Nagase et al. As discussed previously, however, Chano et al. does not qualify as prior art. As such, the Examiner cannot rely on Chano et al. The Examiner's reliance on Chano et al. does not fall within one of the exceptions under M.P.E.P. 2124, and, therefore, cannot be relied upon in this rejection.

Applicants' arguments have been considered, but have not been found persuasive because the nucleic acid of Nagase, which is 99.3 % identical to SEQ ID NO:3 would predictably hybridize to SEQ ID NO: 3 under the stringent conditions of claim 5. As claim 5 is not drawn to the protein with the function of RB1CC1, the evidence of Chano et al is no longer relied upon for the rejection. However, it is noted that a reference used to show an inherent property need not antedate the filing date, see MPEP 2131.01 (III).

Applicants argue that it is further noted that the cited references do not alone or in combination, describe the presently claimed vector or the function of RB1CC1. The vector of the present invention is used for expression of the gene. Persistent high expression and/or

suppression of expression of the RB1CC1 gene may cause damage to cell proliferation or growth. This information is not disclosed in the cited references. Applicants argue that thus, making a vector comprising the RB1CC1 gene would be difficult for one of ordinary skill in the art based on the teachings of Nagase et al. and/or Chano et al. Accordingly, the cited references do not teach or suggest the claimed vector.

Applicants' arguments have been considered, but have not been found persuasive because no function is claimed for SEQ ID NO: 3 in claim 5. Additionally, given that Nagase was able to isolate cells clones with KIAA0203 in them, isolating the vector does not appear to be a problem and is well within the skill of one of ordinary skill in the art.

Applicants' arguments have not been found persuasive and the rejection is maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 10 remains rejected under 35 U.S.C. 103(a) as being unpatentable over AB059622 (October 11, 2001), in view of Mensink et al (British J. Haematol. (August 1998) 102:768-774) and further in view of Buck et al (Biotechniques (1999) 27(3):528-536) for the reasons forth in the Office Action of April 28, 2008, section, 7, pages 6-7.

Applicants argue that claim 10 has been amended to recite primers set forth in "SEQ ID Nos: 5 to 37" instead of "5 to 132." Applicants argue that as described in the present application,

the primers set forth in SEQ ID NOs: 5 to 37 are selected for analysis of human RB1CC1 gene and/or clinical examination relating to cancer. The cDNA of the nucleic acid encoding the novel protein RB1CC1 according to the present invention was obtained by identifying a gene expressing differentially in U-20S osteosarcoma cells and MDR-variant induced cells, conducting amplification employing U-20S mRNA as a template using nucleic acid primers described in SEQ ID Nos: 5 to 37, and determining the amino acid sequence coded for by cDNA of the novel protein and the base sequence (present application, pages 11-12). It should be noted that the function of human RB1CC1 gene must be determined in order to select primers for RB1CC1. None of the cited references describe the function of human RB1CC1. As such, selecting primers for RB1CC1 would not be obvious to one of ordinary skill in the art.

Applicants' arguments have been considered, but have not been found persuasive because the selection of nucleic primers based on a known sequence does not require knowledge of the function of the encoded protein, as knowledge of the sequence is sufficient for primer design for one of ordinary skill in the art. Thus, regardless of the method used by the Applicants to make the primers, the primers would be obvious in view of the prior art.

Applicants' arguments have not been found persuasive and the rejection is maintained.

5. Claims 4, 5, 8, and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over AB059622 (October 11, 2001) as evidenced by Chano et al. (Oncogene, February 14, 2002, 21:1295-1298, IDS), in view of US Patent No. 4,889,806 (Dec. 1989) and Sambrook et al (Molecular Cloning, A Laboratory Manual, Cold Spring Harbor, 1989, pp.16.3-4) for the reasons forth in the Office Action of April 28, 2008, section 9, pages 10 -12.

Examiner argued:

AB059622 teaches as previously set forth in the Office Action of October 11, 2007, section 14, pages 24-25, but does not teach a recombinant vector comprising SEQ ID NO: 3, a transformant transformed with the recombinant vector, or a method for producing protein using the recombinant vector.

US Patent No. 4,889,806 teach that with the advent of recombinant DNA and molecular cloning technology it is now conventional to transfer genetic information into plasmids or vectors constructed in vitro and then transferred into host cells and clonally propagated (col. 1, lines 18-24).

Sambrook et al teach that cloned genes are conventionally expressed using expression vectors and that expression of cloned proteins have been used to: (1) confirm the identity of a cloned gene by using immunological or functional assays to detect the encoded protein; (2) produce large amounts of proteins of biological interest that are normally available in only limited quantities from natural sources; (3) to study the biosynthesis and intracellular transport of proteins following their expression in various cell types; and (4) to elucidate structure-function relationships by analyzing the properties of normal and mutant proteins (para bridging pages 16.3 and 16.4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a recombinant vector with the nucleic acid sequence of AB059622, transform the vector into a host cell and produce a protein with the methods of Sambrook et al and US Patent No. 4,889,806 because US Patent No. 4,889,806 specifically teaches that it is conventional to transfer genetic materials into plasmids or vectors and then transfer the plasmids or vectors into host cells and clonally propagate the genetic material and because Sambrook et al teach that cloned genes are conventionally expressed using expression vectors.

One of ordinary skill in the art at the time the invention was made would have been motivated to make a recombinant vector with the nucleic acid sequence of AB059622 with the methods of Sambrook et al and US Patent No. 4,889,806 because Sambrook et al specifically teach that expressed cloned proteins are used to: (1) confirm the identity of a cloned gene by using immunological or functional assays to detect the encoded protein; (2) produce large amounts of proteins of biological interest that are normally available in only limited quantities from natural sources; (3) to study the biosynthesis and intracellular transport of proteins following their expression in various cell types; and (4) to elucidate structure-function relationships by analyzing the properties of normal and mutant proteins. Given the conventional nature of the methods, one of skill in the art would have had a reasonable expectation of success.

Applicants argue that as described previously, the Examiner cannot rely on the teachings of Chano et al. because Chano et al. does not qualify as prior art. Furthermore, none of the cited references describe the function of RB 1CC 1. Persistent high expression and/or suppression of expression of RB1CC1 gene may cause damage to cell proliferation or growth. This information is not disclosed in the cited references. Thus, making a vector comprising the RB1CC1 gene

would be difficult for one of ordinary skill in the art based on the teachings of the cited references.

Applicants' arguments have been considered, but have not been found persuasive a reference used to show an inherent property need not antedate the filing date, see MPEP 2131.01 (III), thus Chano et al. can be relied upon to show the inherent properties of the protein encoded by AB059622. Additionally, it would be well within the abilities of one of ordinary skill in the art to use the appropriate vectors and/or growth conditions to allow for production of the vector containing AB059622.

6. No claims allowed.

7. All other objections and rejections recited in the Office Action of April 28, 2008 are withdrawn.

8. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal form, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R., 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R., 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Peter J Reddig/

Examiner, Art Unit 1642

/Karen A Canella/

Primary Examiner, Art Unit 1643